

**Nelson, Bettie L**

---

**From:** Kimberly Prchal [Kimberly.Prchal@mdsps.com]  
**Sent:** Friday, January 17, 2003 1:11 PM  
**To:** Mark Likness; Jan.Oey; Bettie.L.Nelson; Candace.R.Adams  
**Cc:** Megan Mccrory; William Bumgardner; Mary Hetrick; Chad Jaeger; Hans-Juergen.Roethig; martin.unverdorben  
**Subject:** Re: Device Count  
**Sensitivity:** Confidential

Mark,

I have redistributed the e-mail regarding the battery safety concerns to our associates.

As for the labels, in order to keep the devices with their respective subjects, these need to stay on the device. This was easy with the short term studies but with this study, because of the short supply of devices and the definite possibility of not receiving the same devices back at each site, at each shipment, the labels will need to be removed after each usage.

Mary and William,  
Will you assure that the labels are removed after you download and prior to each shipment back to Mark for cleaning? Can we also look into getting different labels, less sticky?

Mark, will we have to initialize prior to every collection since we probably will not get the same devices each time?

Kim

Folks,

Just opened the box of opticals from MDS. Couple of concerns...

There was a bag of batteries sent back... I had sent out a warning about this a little while back (not sure if MDS was on distribution) -- batteries could possibly short out when packed together in a bag and thus cause a fire (particularly a problem with these high-capacity lithium batteries). I am recommending that no site \*ever\* send batteries back to us (unless we ask for them because they are faulty or something).

Secondly, the few devices I took a look at did not have battery doors. I realize this was due to accommodating the larger work-around batteries. Are the doors in the box somewhere? The mechanicals came back from Parexel with their doors in a separate bag.

Finally, nearly every device we received this week has one or more labels applied. It is very (very) labor intensive to effectively remove the labels as most are 'permanent' labels. This applies to the mechanicals from Parexel and the opticals from MDS. In order to meet the quick turn around, I want to know if we can leave the labels on the devices. If we must fully remove the labels, it will add dramatically to the prep time for all of these units... This will also drive up the reprocessing cost accordingly. I realize there are frequently good reasons to place labels on the devices, but maybe we can find a more universal solution to this 'sticky' issue (couldn't resist).

-Mark

-----Original Message-----

From: Kimberly Prchal [mailto:Kimberly.Prchal@mdsps.com]

Sent: Thursday, January 16, 2003 8:49 PM  
To: Mark Likness; Jan.Oey; Bettie.L.Nelson; Candace.R.Adams  
Cc: Megan Mccrory; William Bumgardner; Mary Hetrick; Chad Jaeger;  
Hans-Juerger.Roethig@pmusa.com; martin.unverdorben@pmusa.com  
Subject: Re: Device Count  
Sensitivity: Confidential

All,

I have discovered something. The SCoR 6 continuation had it's last topography collection on 12 Jan. So, we can use the older optical devices from that study. We did an inventory and we have 73 devices to ship to Mark. (the other 7 are still out with subjects). Mary has downloaded these and has sent all 73 devices to Mark for receipt tomorrow.

By my calculations, we need a total of 87 devices (not counting extras in case of failures), if we want each subject to have their own, 55 manual and 32 optical. With the SCoR 6 shipment, we should have enough for all 32 subjects to have their own, plus extra in case of failures. Lets say 3 extra devices for all groups. Immediately, at least 11 of the 32 should be cleaned and sent to PHX (2P1). By 01 Mar, at least 17 should be cleaned and sent to LNK (1L1), by 20 Mar, at least 9 should be cleaned and sent to LNK (1) and by 03 Apr, at least 7 should be cleaned and sent to PHX (2P). This would mean that 44 of the 73 old optical devices would be needed for this study AND that we would not have to ship these back to Mark between each group's visit!

For the modified devices, as stated below, Mark has 36 devices available, after cleaning. I would suggest sending 15 to PHX (2P1) immediately, for receipt on 22 Jan. After completion, PHX will send the 15 back to Mark, Mark will clean and send all 36 to LNK for the 1L1 return on 01 Mar and the Group 1 return on 20 Mar. I figure that we will use 26 on 01 Mar, Group 1L1, and the other 10 on 20 Mar, Group 1. If we have to use part of the 10 set aside for Group 1 on Group 1L1 (due to failure), we will send those devices back for cleaning on 03 Mar and Mark will have to return on 10 Mar. If not, all 36 will be returned to Mark for cleaning and delivery of the next round.

I have attached an Excel file that attempts to track shipment/cleaning of devices. Please review and let me know if you have comments. I tried to keep shipments on Mondays. Due to holidays, I have pushed up some shipment dates.

Is there any way we can get our hands on enough modified devices to end the nightmare of shipping between groups?

Hope this helps, let me know what you think. Feel free to correct and re-send to all if needed.

For MDS associates, this is in the McCoy drive.

Thanks  
Kim

Kimberly M. Prchal  
Senior Project Manager  
MDS Pharma Services - Lincoln, NE  
kimberly.prchal@mdsps.com  
402.437.4773

Folks,

Per our conversation yesterday I am working to get 12 modified (for Accord) devices ready to ship to Phoenix. I assume MDS is sending 10 optical devices 8 of which will be cleaned and sent to Phoenix as well.

We need the MDS devices ASAP so we can turn them around.

We received 35 modified (for Accord) devices from Parexel yesterday. We have one additional modified (for Accord) device here that was repaired some time ago. That gives us a total of 36 (rather than 38). Somewhere out there are 4 additional modified devices... I believe the engineering crew has three of them and I am not sure where the other one is at this point. To meet the 26 modified (for Accord) devices to MDS \*before\* March 1 requirement we will need to get those devices back in here.

Call email if this is not making sense. Thanks.

-Mark

-----  
Mark Likness, President/CEO  
Plowshare Technologies, Inc.  
3500 Boston St, MS55, Suite 311  
Baltimore, MD 21224  
-----

~ phone 410.342.5947 ~ fax 410.342.6618 ~ cell 410.215.9002  
~ MarkL@plowshare.com ~ <http://www.plowshare.com/>